

REMARKS

The Official Action of June 2, 2006, and the prior art cited and relied upon therein have been carefully reviewed. Applicants appreciate the thoroughness of the examination. The claims in the application are now claims 1, 3-5, 9 and 13, and these claims define patentable subject matter warranting their allowance. The applicants accordingly respectfully request favorable reconsideration and allowance.

Acknowledgement by the PTO of the receipt of applicants' papers filed under Section 119 is noted.

The Office Action states that the Information Disclosure Statement filed with the present application on September 24, 2003, does not comply with the rules, and therefore the foreign prior art cited therein has not been considered. The position of the PTO is respectfully traversed in this regard.

The prior art documents cited in the Information Disclosure Statement filed with the present application on September 24, 2003, is the same prior art which was cited in the parent application 10/354,985. Applicants are claiming the benefit of the parent application 10/354,985 under 35 USC 120. Consequently, the IDS as filed was fully in accordance with the rules per 37 CFR 1.98(d)(i) which states as follows:

A copy of any patent, publication,
pending U.S. application or other

information, ... listed in an Information Disclosure Statement is required to be provided, even if the... information was previously submitted to, or cited by, the Office in an earlier application, **unless**:

- (1) The earlier application is properly identified in the Information Disclosure Statement and is relied on for an earlier effective filing date under 35 USC 120;...
[emphasis added]

Such prior art was properly cited in the parent application, where a concise explanation or abstract or the like for each such document was already provided. Applicants accordingly understand that their IDS submission of September 24, 2003, in the present application meets all the requirements of the PTO because the corresponding information was already provided in the parent application upon which the present applicants rely under §120.

Applicants therefore request the PTO to give full consideration to the documents listed in the IDS filed September 24, 2003. Applicants respectfully request the PTO to provide applicants with a fresh copy of the IDS form in question in which the examiner's initials appear in the left hand column adjacent citations AB, AC and AD, showing that these documents have indeed been given consideration by the PTO.

As regards paragraph 3 spanning pages 2 and 3 of the Official Action, applicants note that they have filed **both** an ADS and an appropriate first paragraph of the specification. Benefit under §120 is achieved by either the ADS or the first paragraph of the specification. As regards priority under §119, applicants

have made the claim for priority, and the claim has been acknowledged. As helpfully suggested by the examiner, the status of the parent application has now been updated in the first paragraph of the specification.

New claim 13 has been added, support being found in applicants' specification in paragraphs [0031] and [0032], as well as paragraphs [0059] and [0060]². Claim 13 defines patentable subject matter for the reasons given below.

Claims 1-12 have been rejected under the second paragraph of §112. The rejection is respectfully traversed.

Claims 8 and 12 have now been deleted, and claim 4 has been amended to specify polyethylene glycol.

Claim 5 and the claims which depend therefrom specify that the susceptible disease is a "TNF- α susceptible disease". This is clearly understandable to those skilled in the present art. TNF- α susceptible diseases are moreover defined in paragraph [0021] of applicants' specification as diseases which can be treated and/or prevented by administration of TNF- α .

Applicants do not understand part "C" of the rejection which includes the rejection of claim 5 which does not depend from claim 2, and which rejection then only mentions claim 2. At any rate, claim 1 has now been amended to incorporate the features of claim 2, and the language in question has now been

² See the publication of Applicants' specification, U.S. 2005/013795 A1.

further amended to specify that Xaa is the same or different. It is clear that Xaa can be the same or a different member selected from eight (8) amino acid residues, noting paragraphs [0015] and [0016] of applicants' specification.

Claim 1 from which all of the other claims depend (and therefore incorporate the subject matter of claim 1) now recites that the polymer is water soluble, and the language "high molecular" has been deleted.

Claim 1 has also been amended to specify that the binding is "covalent".

Claim 1 has been further amended to deleted the wording "TNF activity". In addition, the language abstracted from claim 2 and inserted into claim 1 has been further amended to specify that the proteinaceous part has a TNF- α activity. The meaning of this terminology is absolutely clear from a reading of applicants' specification (again see for example paragraph [0021]), applicants respectfully noting that the law is clear that claims are to be considered in light of an applicant's specification. TNF is of course well known as being short-hand for "Tumor Necrosis Factor", such factor being a biologically active substance having certain biological activities; one such activity is an anti-tumor activity as shown in example 3 of applicants' specification. Applicants' claims are clear and the rejection should be withdrawn.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1-12 have been rejected under the first paragraph of §112 as not complying with the written description requirement. Such rejection is respectfully traversed.

First, those claims are all original claims, and they therefore inherently broadly comply with the written description requirement. Nevertheless, certain amendments, at least mostly of which have been mentioned above in reply to the rejection under the second paragraph of §112, have been made to better comply with U.S. practice. In particular relative to the "Written Description" rejection, claim 1 has been amended to define that the proteinaceous part comprises an amino acid sequence SED ID NO: 2 wherein Xaa is a member selected from among the eight (8) specified amino acid residues. For the record, all the amendments are made without prejudice, applicants reserving the right to pursue broader claims in a continuing application, without any penalty whatsoever, applicants in such a case relying on §§120 and 119.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 5-12 have been rejected under the first paragraph of §112 as lacking enablement as regards the scope of those claims. The rejection is respectfully traversed.

Applicants have remarked above that the meaning of TNF- α susceptible diseases would be understood by those skilled in the art, particularly upon reading applicants' specification, and that this is fully in accordance with the law. In deference to the examiner's views, it has now been made explicit in claim 5 that the susceptible diseases in question are TNF- α susceptible diseases. The form of claim 5 is also amended to change from an "agent" claim to a "method for treating" claim.

Withdrawal of the rejection is in order and is respectfully requested.

Applicants note that claims 1-4 were not rejected under the first paragraph of §112 as lacking enablement. Applicants agree, and are proceeding in reliance thereof.

Claims 1, 3-5, 7-9, 11 and 12 have been rejected under §102 as anticipated by Yu et al USP 6,541,224 (Yu). This rejection is respectfully traversed.

Claim 2 has not been included in this rejection, and indeed has not been rejected on the basis of any prior art either under §102 or §103. Accordingly, applicants understand that claim 2 is deemed by the PTO to define novel and un-obvious subject matter under §§102 and 103.

As noted above, claim 2 has been incorporated into claim 1. Accordingly, applicants need not further address the rejection based on §102 as claim 1 now corresponds to claim 2,

Appln. No. 10/668,178
Amd. dated September 5, 2006
Reply to Office Action of June 2, 2006

and as all of the other claims in the application depend from and incorporate the subject matter of claim 1 as amended above to include the features of novel and un-obvious claim 2.

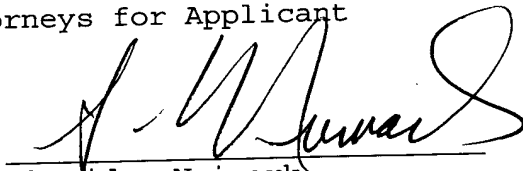
The prior art documents of record and not relied upon by the PTO have been noted, along with the implication that such documents are deemed by the PTO to be insufficiently material to warrant their application against any of applicants' claims.

Applicants believe that all issues raised in the Office Action have been addressed above in a manner favorable to allowance of the present application. Accordingly, applicants respectfully request favorable reconsideration and early formal allowance.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By


Sheridan Neimark
Registration No. 20,520

SN:kg
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\S\SUMA\MAYUMI2A\PTO\2006-09-05 AMD.doc